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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	10/600,548	VOGT ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said coating being introduced into a porous system" in lines 10 and 11. However, this phrase renders the claim indefinite, since it is unclear whether the coating exists internally within the porous bodies or externally (such as on the surface of the porous bodies) or whether the coating exists both internally and externally.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 6-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draenert (US 4,713,076) in combination with Greco et al. (US 4,749,585).

In claim 1, applicant claims "antibiotic coated porous bodies, comprising a coating made of at least one antibiotic salt that is hardly soluble in water or in an aqueous environment from the group consisting of the netilmicin laurate, the netilmicin dodecyl sulfate, the netilmicin

myristate, the sisomicin laurate, the sisomicin myristate, the sisomicin dodecyl sulfate, the gentamicin laurate, the gentamicin myristate, the clindamycin laurate, the amikacin laurate, the amikacin myristate, the amikacin dodecyl sulfate, the kanamycin laurate, the kanamycin myristate, the kanamycin dodecyl sulfate, the vancomycin laurate, the vancomycin dodecyl sulfate, the vancomycin myristate, the vancomycin teicoplanin, the tobramycin laurate, the tobramycin myristate, the tobramycin dodecyl sulfate, the ciprofloxacin laurate, the ciprofloxacin myristate and the clindamycin teicoplanin, said coating being introduced into a porous system of non-metallic porous bodies and/or of metallic porous bodies. Claims 6-15 are drawn to antibiotic coated porous bodies comprising specific forms, coating contain additional antibiotics, reabsorbable porous bodies, binding agents and implants containing the antibiotic coated porous bodies.

Draenert discloses that antibiotics can be added to the coating of porous spherical particles (porous bodies) and that said composition can be used for implants (see claim 6, see col. 6, lines 54-66, and abstract). Draenert discloses that antibiotics in general can be used, that the coating can be are fully reabsorbable (col. 2, lines 65-68), reabsorbable binding agents can be used (col. 4, line 60 to col. 5, line2) and that the antibiotic coated porous bodies can be used in implants.

Greco et al. disclose an improved prosthesis coated with an ionic surfactant, an antibiotic and/or antithrombiotic agent and treated with an immobilizing ionic exchange compound, to remove un-antibiotic bound ionic surfactant (see abstract). In addition, Greco et al. disclose that the antibiotic can be gentamycin, vancomycin or clindamycin (see col. 3, lines 17-42) and the surfactant can be sodium laurate sulfate (see col. 2, lines 25-50).

The difference between applicant's claimed composition and the composition of Draenert is that Draenert doos not disclose the specific antibiotics that can be used in the coating of the porous bodies. However, Greco et al. disclose that antibiotics (such as gentamicin, vancomycin or clindamycin) may be combined with a surfactant (sodium laurate sulfate) to be used in coating of prosthesis (which include implants). This suggests that antibiotics such as gentamicin laurate, vancomycin laurate, or clindamycin laurate may be combined with a surfactant such as sodium laurate sulfate in coating of prosthesis (which include implants).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the composition disclosed by Draenert that comprises porous spherical particles with antibiotic coating (antibiotic coated porous bodies) and to use the specific antibiotics (gentamicin, vancomycin or clindomycin) and surfactant (sodium laurate sulfate) which is disclosed by Greco et al., in order to produce applicant's antibiotic coating (gentamicin laurate, vancomycin laurate or clindomycin laurate) to be used on prosthesis (such as implants).

One having ordinary skill in the art would have been motivated, to prepare the composition disclosed by Draenert that comprises porous spherical particles with antibiotic coating (antibiotic coated porous bodies) and to use the specific antibiotics (gentamicin, vancomycin or clindomycin) and surfactant (sodium laurate sulfate) which is disclosed by Greco et al., in order to produce applicant's claimed antibiotics (gentamicin laurate, vancomycin laurate or clindomycin laurate) to coat prosthesis (such as implants), as set forth in the prior art..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draenert (US 4,713,076) in combination with Greco et al. (US 4,749,585)

In claim 2, applicant claims "Method for producing antibiotic coated porous bodies pursuant to claim 1, comprising introducing first an aqueous solution, containing at least one representative of an easily water soluble salt of at least one of netilmicin, sisomicin, clindamycin, amikacin, kanamycin, tobramycin, vancomycin, and ciprofloxacin, into the porous system of porous bodies and that after a drying phase introducing a second aqueous solution of an easily water soluble salt of lauric acid, myristic acid and/or dodecyl sulphuric acid and thereby developing a hardly water soluble antibiotic coating in the porous system of the porous body." Dependent claims 3-5 are drawn to the use of specific solutions containing the antibiotics, reversing the introduction steps, and evaporating the solvents (such as the alcohols, methanol and ethanol).

Draenert discloses a method of coating porous spherical particles (porous bodies) which can be used for implants (see claim 6, see col. 6, lines 54-66, and abstract). In addition, Draenert discloses that antibiotics can be added to the coating of the said composition (see claim 6, see col. 6, lines 54-66, and abstract). Draenert discloses that solvents like alcohols can be used and the composition can be dried (which includes drying by heating or evaporating) (col. 7, line 68 to

col. 8, line 11) and the reversals of the claimed steps should not affect the product formed and thus appears to be a matter of choice.

Greco et al. disclose an improved prosthesis coated with an ionic surfactant, an antibiotic and/or antithrombiotic agent and treated with an immobilizing ionic exchange compound, to remove non-antibiotic bound ionic surfactant (see abstract). In addition, Greco et al. disclose that the antibiotic can be gentamycin, vancomycin or clindamycin (see col. 3, lines 17-42) and the surfactant can be sodium laurate sulfate (see col. 2, lines 25-50).

The difference between applicant's claimed method and the method of Draenert is that Draenert doos not disclose the same antibiotics used by applicant in the coating of the porous bodies. However, Greco et al. disclose that antibiotics (such as gentamicin, vancomycin or clindamycin) may be combined with a surfactant (sodium laurate sulfate) to be used in coating of prosthesis (which include implants). This suggests that applicant's antibiotics may be obtained by combining antibiotic and surfactant in coating of prosthesis (which include implants).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of Draenert to prepare the composition disclosed by Draenert that comprises porous spherical particles with antibiotic coating (antibiotic coated porous bodies) and to use the specific antibiotics (gentamicin, vancomycin or clindomycin) and surfactant (sodium laurate sulfate) which is disclosed by Greco et al., to produce applicant's antibiotic coating (gentamicin laurate, vancomycin laurate or clindomycin laurate) to be used on prosthesis (such as implants).

One having ordinary skill in the art would have been motivated, to use the method of Draenert to prepare the composition disclosed by Draenert that comprises porous spherical particles with antibiotic coating (antibiotic coated porous bodies) and to use the specific

antibiotics (gentamicin, vancomycin or clindomycin) and surfactant (sodium laurate sulfate) which is disclosed by Greco et al., to produce applicant's antibiotic coating (gentamicin laurate, vancomycin laurate or clindomycin laurate) to be used on prosthesis (such as implants).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

August 6, 2004.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600